K010177

MAY 1 7 2001

SUN BIOMEDICAL LABORATORIES, INC.

604 VPR CENTER, 1001 LOWER LANDING ROAD, BLACKWOOD, NJ 08012
Tel. 856-401-1080 Fax. 856-401-1090

510(k) CONTENT SUMMARY

1. Name of Manufacturer:

   Sun Biomedical Laboratories, Inc.
   604 VPR Center, 1001 Lower Landing Rd.
   Blackwood, NJ 08012

2. Trade Name: Visualine®II (also known as SunLine®) Amphetamine Assay

3. Common Name:

   An in-vitro immunoassay test by visual color comparison for the detection of Amphetamine in human urine samples. **This test is to be used for professional use only.**

4. Regulation # and Classification:

   Reg. #862-3170, Class II Device

5. Test Description:

   The Visualine®II (also known as SunLine®) Amphetamine test is based on the principle of antigen-antibody complexation and is used for the analysis of Amphetamine in urine samples. The assay utilizes a competitive immunochromatographic technique involving a sample of test urine delivered in a sample well on the device that holds the porous membrane. When the drug is present in the urine test sample, the drug or drug metabolite competes for the limited antibody sites on the colored microspheres. When an adequate amount of drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored microspheres to the probe site on the membrane. Therefore, a positive urine sample will inhibit the formation of precipitin at the probe site.

   A reference or control line with a secondary antibody reaction is added to the membrane strip to indicate that the sample is properly wicking on the membrane. This control line should always be present. A negative urine sample will produce two colored lines and a positive urine sample will show only one, the control line.

6. Comparison of Two Test Systems for Correlation Studies:

The Visualine®II Amphetamine assay is correlated to Gas Chromatography/Mass Spectroscopy. The following table illustrates the similarities and differences between the two assays.

	GC/MS	Visualine®II Amphetamine
Test Principle	Gas Chromatography/Mass Spectroscopy	Competitive binding immunoassay
Sample/Sample Size	2 ml urine	Approx. 150 *u*L (3 drops) urine
Antibody	n/a	Monoclonal
Tracer	Deuterated analyte	Ab Colloidal Complex
Detection Method	Mass Spectroscopy	Visual color precipitin formation
Test Run Time	Methodology specific	5 minutes
Storage Requirement	n/a	2-30°C (36-86°F)
Detection Level	200 ng/ml	1000 ng/mL Amphetamine
Ancillary Equipment	Shimadzu QP 5000	none

7. Visualine®II Amphetamine Performance Characteristics

A. Correlation studies between Shimadzu QP 5000 GC/MS and the Visualine®II Amphetamine test were conducted at Redwood Toxicology Labs and Sun Biomedical Labs, Inc. The GC/MS testing was done at Redwood Labs. The positive samples were then sent to Sun Biomedical where the Visualine™ Amphetamine was performed. Correlation with Shimadzu QP 5000 GC/MS using a cutoff value of 1000 ng/mL Amphetamine yielded the following data:

Sensitivity	50/52	=	96.0%
Specificity	78/78	=	100%
Efficiency	128/130	=	98.5%

Two specimens tested as borderline positives when tested by the Visualine™ II test and rendered GC/MS values of 1,100 ng/ml, and 1,125 ng/ml.

B. Specificity and Substances Detected:

The test is specific to Amphetamine or structurally related compounds. The test detects Amphetamine at a concentration of 1000 ng/mL.

C. Visualine®II Amphetamine Sensitivity:

The test is 100% sensitive at 1000 ng/mL Amphetamine at 5 minutes.

D. Precision: Reproducibility studies indicate:

Within run and run to run	> 99%
Within day and day to day	> 99%
Within lot and lot to lot	> 99%

E. Stability Statement:

Visualine®II Drug Urine Tests have been studied with respect to stability. The drug urine tests are tested every three months for up to a period of over two years. Visualine®II Amphetamine test kits are stable within their marked expiration date and under the storage conditions as described in the insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 17 2001

Ming Sun, Ph.D.
President
Sun Biomedical Labs, Inc.
604 VPR Center
1001 Lower Landing Road
Blackwood, NJ 08012

Re: 510(k) Number: K010177
Trade/Device Name: SunLine® Amphetamine Test and Visualine ® Amphetamine Test
Regulation Number: 862.3100
Regulatory Class: II
Product Code: DKZ
Dated: April 6, 2001
Received: April 27, 2001

Dear Dr. Sun:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SUN BIOMEDICAL LABORATORIES, INC.

604 VPR CENTER, 1001 LOWER LANDING ROAD, BLACKWOOD, NJ 08012
Tel. 856-401-1080 Fax. 856-401-1090

510 (k) Number: K010177

DEVICE NAME: SunLine® Amphetamine Test

INDICATIONS FOR USE: The SunLine® Amphetamine Assay is used for qualitative testing for the presence of Amphetamines in urine samples at 1000 ng/ml. This test provides only a preliminary screening result; a more specific alternative method should be used to confirm the test result. This test is intended for use by medical professionals.

Dan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010177

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ (Per 21 CFR 801.109) OR Over-The-Counter-Use _____ (Optinal Format 1-2-96)

SUN BIOMEDICAL LABORATORIES, INC.

604 VPR CENTER, 1001 LOWER LANDING ROAD, BLACKWOOD, NJ 08012
Tel. 856-401-1080 Fax. 856-401-1090

510 (k) Number: K010177

DEVICE NAME: Visualine® Amphetamine Test

INDICATIONS FOR USE: The Visualine® Amphetamine Assay is used for qualitative testing for the presence of Amphetamines in urine samples at 1000 ng/ml. This test provides only a preliminary screening result; a more specific alternative method should be used to confirm the test result. This test is intended for use by medical professionals.

Dan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010177

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use _____ (Optinal Format 1-2-96)